

**MEMBRANE ERASER**

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates to a membrane eraser (hereinafter, called an ophthalmic treatment tool) and, in  
5 more detail, to a new instrument which is useful for removing proliferative membranes in a treatment for proliferative vitreoretinal disorders.

2. Description of the Background

A continuing challenge to vitreoretinal surgeons is the  
10 separation of proliferative membranes from the neurosensory retina without injury or harm to the neurosensory retina in the treatment for proliferative vitreoretinal disorders. For such a treatment, the removal of proliferative membranes from the surface of the retina is required in a wide variety of  
15 pathologic conditions and surgical situations. Various intraocular picks and intraocular forceps have been previously used for the removal of proliferative membranes.

[However, the way that proliferative membranes are removed by the above conventional instruments may carry the  
20 risk of causing damage to the retina at all times. Besides,

there is a problem as follows. That is, "immature proliferative membranes" seen in proliferative vitreoretinal disorders may be friable, difficult to peel off as films, and often cannot be sufficiently removed from the surface of the retina, so that the unremoved or remaining proliferative membranes can be the source of subsequent re proliferation and thus the likelier it become that the re proliferative membranes again require the removal thereof as time elapses.] However, removal of the proliferative membranes by these conventional methods carries the risk of damage to the retina. Moreover, "immature proliferative membranes", common in proliferative vitreoretinal disorders, may be friable and difficult to peel off as films. These immature membranes often cannot be sufficiently removed from the surface of the retina with the conventional instruments. Consequently, the unremoved or remaining proliferative membranes are a source of subsequent re proliferation, requiring later operations for removal and correction.

#### SUMMARY OF THE INVENTION

It is, therefore, an object of the invention to provide a new instrument which can solve the foregoing problems regarding the instruments of the prior [arts and can be] art and is useful for removing proliferative membranes in a treatment for proliferative vitreoretinal disorders.

[This object is achieved by the] The present invention [as follows: the invention] is directed to an ophthalmic treatment tool for [using] use in [an] ophthalmic surgery, which [comprises: a grip portion; a rod-shaped body attached to one end of the grip portion; an elastic body fitted along a direction toward a front end of the rod-shaped body to the front end side of the rod-shaped body; and a plurality of hard inorganic fine-grains or particles fixed on a tapered front tip of the elastic body] has a grip portion, a rod shaped

body, and an elastic body. The rod shaped body has opposite first and second ends, with the first end operably attached to the grip portion and the second end extending away from said grip portion to the elastic body. The elastic body has

5 opposite proximal and distal ends and a hollow interior. The hollow interior at the proximal end is adapted to operably attach to the second end of the rod-shaped body. The distal end has a tapered tip extending away from the rod shaped body. The ophthalmic treatment tool also includes a plurality of

10 hard, inorganic fine-grains fixed on the tapered distal tip of the elastic body. The fine-grains are configured for removal of membrane tissue on a retina of an individual.

[According to the ophthalmic treatment tool with] With an ophthalmic treatment tool having the construction mentioned

15 above, it is possible to more appropriately separate and remove proliferative membranes [consisting of] , having a thin and delicate [tissues] consistency, from the retina while [more] remarkably reducing the risk of [causing] damage to the retina [or of] in the form of a [forming the] retinal tear,

20 [in contradistinction to the case of the conventional instruments being used] when compared to the use of conventional instruments. Various other objects, features and attendant advantages of the present invention will be more fully appreciated as the same becomes better understood from

25 the following detailed description when considered in connection with the accompanying drawings in which like reference characters designate like or corresponding parts throughout the several views and wherein:

### 30 BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1a is a side view of an ophthalmic treatment tool of one embodiment according to the present invention;

FIG. 1b is a partially enlarged view of the ophthalmic treatment tool in FIG. 1a;

FIG. 1c is a front view of a distal tip [portion] of the elastic body of the ophthalmic treatment tool in FIG. 1a;

FIG. 2a is a side view of an ophthalmic treatment tool of [the other] another embodiment according to the present invention;

FIG. 2b is a partially enlarged view of the ophthalmic treatment tool in FIG. 2a; and

FIG. 2c is a front view of [a] the distal tip [portion] of the elastic body of the ophthalmic treatment tool in FIG.

10 2a.

#### DESCRIPTION OF THE PREFERRED EMBODIMENT

The invention will now be more specifically described with reference to embodied configurations illustrated in the drawings attached hereto, but the present invention should not be restricted to those embodied configurations.

[Referring to FIGS. 1a to 1c and FIGS. 2a to 2c, among those figures are FIG. 1a which is a side view of an ophthalmic treatment tool of one embodiment according to the present invention, FIG. 1b which is its partially enlarged detail, FIG. 1c which is a front view of a tip portion of the ophthalmic treatment tool, and FIGS. 2a to 2c which are views showing a configuration according to a modification of the tool shown in FIGS. 1a to 1c.

An ophthalmic treatment tool of the present invention, as shown in the figures, is characterized by having a grip 1, a rod-shaped body 2 attached to one end of the grip 1, an elastic body 3 fitted along a direction toward a front end of the rod-shaped body 2 to the front end side of the body 2, and a group of hard inorganic fine-grains 5 of particles fixed on a tapered tip 4 of the elastic body]

An ophthalmic treatment tool of the present invention, as shown in the figures, is characterized by a grip portion 1, and a rod-shaped body 2, having opposite first and second ends 20,22. The first end 20 is attached to the grip portion 1.

The second end 22 has a slender line portion 2' having a reduced exterior diameter from that of the remainder of the rod-shaped body 2. As shown in FIG. 1b, the exterior diameter of the slender line portion 2' is preferably in a range of 0.4mm to 0.6mm and the exterior diameter of the remainder of the rod-shaped body 2 is preferably in a range of 0.9mm to 1.2mm. The slender line portion 2' is configured to receive an elastic body 3 fitted thereon. The elastic body 3 surrounds and extends beyond the slender line portion 2'. The elastic body 3 is provided with a tapered tip 4, having a group of hard, inorganic fine-grain particles 5 fixed thereon.

The grip 1 [can be well] is adapted to be securely grasped by a user's fingers [for a] during surgery[, which]. The shape of the grip 1 is not restricted to the example shown in the figure and may have any shape [unless it troubles the users in their operation] that is comfortable for the user. [In the case of grasp by the fingers, the] The grip 1 is suitably formed to be [mostly] as thick as [e.g., pencils, pens, or chopsticks] common items, which [the users are] the user is generally [used] accustomed to handling, such as a pencil or a pen. [With respect to materials, the] The grip 1 is made from a material which [have no] does not present a hygienic problem[, the]. The material [being, for example,] may be wood, metal, plastic or the like. Preferably, metal is [the metal being preferably] used for the grip, the better of the metals being silver, stainless steel, or titanium [or the like,]. Most preferably, titanium is [the titanium being preferably] used for the grip in [the] light of [the] its strength[, lightweight and/or others] and its light weight.

[One end of the grip portion 1 is fixed to a rod-shaped body 2 in a certain way that may be modified as needed.] The rod-shaped body 2 extends from the distal end 10 of the grip 1. The direction and length of the extension may be modified as required, depending upon the operation. The rod-shaped body 2 is provided for purposes of supporting [an] the elastic

body 3 which is placed on the [front end side] slender line  
portion 2' of the second end 22 of the rod-shaped body 2.

[Although the rod-shaped body 2 is made from any material  
 which creates no problem in terms of of sanitation as is the  
 5 case with the grip 1,] Similar to the grip 1, the rod-shaped  
body 2 is made from a material which presents no hygienic  
problems. Preferably, the rod-shaped body 2 is [preferably]  
 made from titanium [in common reason with] for the same  
reasons as the grip 1.

10 [An end portion of the rod-shaped body 2 is provided with  
 the elastic body 3.] The slender line portion 2' is sized to  
accommodate the elastic body 3. Preferably, [The] the elastic  
 body 3 is translucent and takes the form of a tube, which is  
 fixed to the rod-shaped body 2 by being inserted on [an end 2'  
 15 of the rod-shaped body] the slender line portion 2'. In a  
 configuration shown in the figure, the rod-shaped body 2 is  
 tapered in a part of the [front] second end 22 [side thereof]  
 to form [a] the slender line portion 2' of the rod-shaped body  
 [, and the]. The slender line portion 2' is squeezed into  
 20 [the] a tube-shaped opening 33 in the elastic body 3, whereby  
 the bodies 2,3 [and 3] are fixed to each other. The manner of  
 coupling both, however, should not be restricted to the  
 configuration shown in the figure, to which any type of  
 coupling can be applied [, within] with tight coupling of the  
 25 rod-shaped body 2 and the elastic body 3 [thus] resulting.

The elastic body 3 [is] may be made from any material  
 which [creates] presents no sanitary problems [in ophthalmic  
 surgery as in the cases mentioned above, for]. For example,  
 the material of the elastic body 3 [being] may be natural  
 30 rubber, synthetic rubber, polyurethane rubber, silicone  
 rubber, fluorocarbon rubber, or the like[,]. Preferably, the  
 elastic body [being most suitably] is made from silicone  
 rubber in [the] light of [the] its pliability[,] and inertness  
 (sanitary property)[and so on]. The slender line portion 2'  
 35 is not entirely inserted [into a] through the tube of the

elastic body 3 but stops short, leaving a portion of the tube projecting from the second end 22 of the rod to the tapered tip 4 of the elastic body 3 as seen in FIG. 1b. The portion of the tube of the elastic body 3 projecting from the rod

5 second end 22 gives the elastic body [, whose front end side is thus not inserted on the slender line portion 2'. An elastic portion positioned on the figure's right side from the front end of the slender line portion 2' must be kept in] a sufficiently pliable and flexible [state] distal end so as not

10 to carry the risk of causing damage to the retina [and so on] when peeling [the] membranes from the retina during [the] ophthalmic surgery.

The tip [(in the figure, right end portion)] 4 of the elastic [member] body 3 is formed in a tapered shape. The

15 shape can be easily formed by cutting the tube-shaped elastic body 3 at a bevel. [Although such cutting at a bevel causes a cross-sectional profile as in the case of a bamboo being cut at a bevel] Cutting the elastic body 3, having a cylindrical shape and a tube-like opening 33, results in the cross-

20 sectional profile as shown in FIG. 1c[,]. However, such a profile is not essential for the present invention. For instance, an elastic [portion] body having no tube-like opening for insertion of the slender line portion 2' [may have no space] will not have a tubular extension projecting from

25 the slender line portion 2' of the rod-shaped body 2. In this instance the tip of the elastic body 3 should be tapered only.

[A great number of] Numerous hard inorganic fine-grains 5 are bonded to [adheres around a] the tapered tip 4 of the elastic [member 3,] body 3. The fine-grains 5 are provided

30 around the tip 4. The fine-grains 5 [which have a] function to peel and remove the proliferative membranes on the retina without injury to the retina. The hard inorganic fine-grains used [hereon,] on the tip 4 [should] may consist of any rigid fine-grains or particles which [has] have chemical inertness

35 and present no problem in sanitation. For example, the fine-

grains may be various kinds of fine-grains [which are made of] such as diamond, diamond-like carbon, ruby, sapphire, quartz, crystal, alumina, silica, silicon carbide, silicon nitride, marble, grindstone, or the like[, and the]. The fine-grains 5 [is most suitably] are preferably made of diamond in the light of the chemical inertness and the advantages associated with hygiene[and so on thereof].

The fine-grains 5 may range in size or diameter from 3 $\mu$ m to 80 $\mu$ m, and preferably range between 9 $\mu$ m and 30 $\mu$ m. It has 10 been found that proliferative membranes on the retina would not be sufficiently removed at any rate if the diameter of grains are out of [the] this range.

[A bonding between] The method used to bond the fine-grains 5 [and] to the elastic body is preferably performed by 15 using an [suitable] adhesive chosen in accordance with the nature of the material of the elastic [member] body 3. If the elastic [member] body is made from silicone rubber, a silicone base adhesive is preferably used. In addition to this, if an adhesive of the two-liquid setting type, thermosetting type, 20 or photostetting type is used, the hard inorganic fine-grains are tightly fixed to the elastic body [respectively] after the adhesive constructs bridges to the surface of the elastic body and hardens[as soon as the adhesive makes attachment, and then the adhesive becomes in chemical inertness to have no sanitary 25 problem]. Upon hardening, the adhesive must become chemically inert to prevent sanitary problems. The choices of an adhesive, of course, should not be restricted to the preferred examples mentioned above. A bonding of the hard inorganic fine-grains can be performed in [any] many well-known [way] 30 ways. However, it is desirable that the surfaces of the fine-grains are exposed externally[, which are among the hard inorganic fine-grains bonded and fixed, are] and not covered with the adhesive. [The] Preferably, the bonding of the fine-grains[, namely, is desirably] is performed as follows: 35 first, an appropriate adhesive is attached to the tip of the

elastic [member] body; secondly, the hard inorganic fine-grains are [strewn] dispersed on a surface of the attached adhesive to cover the surface; thirdly, a process whereby [that] the adhesive constructs bridges from the elastic body  
 5 to the fine-grains and hardens is performed. This process is repeated until the desired coarseness is achieved on the elastic body to allow the [on condition that the fine-grains can be attached no more, to such an extent that a state of the rough surface of the attached group of] fine-grains [have  
 10 activity in] to effectively remove proliferative membranes. Following the completion of the process of constructing bridges and hardening of the adhesive, it is preferable to remove fine-grains loosely attached to the tip of the elastic [member] body (that is, fine-grains which may come off the tip  
 15 during an ophthalmic surgery) by performing an ultrasonic cleaning or similar process [and the like in advance].

Although FIG. 1c shows an example of a range that the hard inorganic fine-grains 5 are fixed to the tapered portion 4 of the elastic [member] body 3, the example is merely one  
 20 example. [Such a range is not restricted to a particular range within keeping activity at removing proliferative membranes on a retina.] The removal of proliferative membranes using the instrument of this invention may require different ranges. The range (x), which has been obtained based on  
 25 experiment and seems to be preferable, has a width between 0.5 and 3 mm [substantially]. The ophthalmic treatment tool according to the present invention is realized as mentioned above. It should be noted that some measurements inscribed in the figures do not limit the present invention but are  
 30 displayed for those skilled in the art to easily understand the invention. Further note that FIG. 2 shows an ophthalmic treatment tool of the other embodiment according to the present invention.

The inventors have used the treatment tool shown in the  
 35 figures for a series of their patients who have undergone an

operation of vitreous removal at their macular hole, and the tool has been applied to a retinal surface around a macular hole after peeling the rear vitreous. Furthermore, the treatment tool shown in the figures has been applied for treatment of the proliferative vitreoretinal disorders with the purpose of removing immature proliferative membranes and pigmented cells from a surface of the retina.

In further detail, the inventors have used the treatment tool shown in the figures for eyes of seven patients which show the macular holes (Gass stages II, III and IV), and as a result, [it has] through use of the tool, the inventors have been able to successfully close the macular holes in all eyes. In three cases of proliferative vitreoretinal disorders, thin friable proliferative membranes were removed effectively. The inventors did not encounter any complications during their experience with the treatment tool shown in the figures. Neither retinal hemorrhages nor retinal tears have occurred, although such results [the treatment tool shown in the figures] are possible with injudicious use.

During the development of the treatment tool according to the present invention, hard inorganic fine-grains (e.g., diamond particles) were occasionally shed onto the retinal surface. However, any shed particles could easily be aspirated and removed by an extrusion needle, and any retained inert diamond particles [are] were deemed unlikely to cause retinal damage or toxicity. The inventors were successful in minimizing the shedding of particles under surgery by introducing a step of sonication cleaning process to previously remove the grains loosely adhering to the tip portion of the elastic body during manufacturing. Currently rarely if ever, has there been observed shedding of the hard inorganic fine-grains.

[The roughened surface of the elastic body which is an extreme] The tip of the treatment tool according to the invention, [the roughened surface being due to existing]

having abrasive fine-grains, allows the proliferative membranes to be removed without the application of high degrees of force on the retina in the removal of the proliferative membranes.

5       The treatment [instrument] tool embodying the present invention differs from rigid instruments such as picks and forceps applying mechanical force to the synechia portion between the proliferative membranes and the retina[.]. The treatment tool has a [whose] slender profile and a  
 10 [flexibility of the] flexible front tip to permit [increases] increased visualization of the area of interest in an ocular tissue during a surgery [and enables], enabling the treatment to be performed properly and easily.

      Since the front tip of the tool, covered with the hard  
 15 inorganic fine-grain particles, [scours] abrades the proliferative membranes, it is readily apparent to those skilled in the art that the proliferative membranes [can be seen to] will separate from the surface of the retina. Even [if a] when the proliferative membranes to be removed [is] are  
 20 remarkably thin, [therefore,] lightly abrading the surgical site with the tool of the present invention will cause changes in the light reflex[,], and color[, and the other detail] of the retina. These indications will tell the surgeon which regions of the proliferative membrane have been separated,  
 25 thus allowing the surgeon [being able to perfectly] to more optimally perform the treatment.

      In the present tool according to the invention, the mechanism as mentioned above makes the tool especially useful for the removal of residual cortical vitreous proliferative  
 30 membranes or retinal interfaces from the surrounding area of a macular hole. The tool is also effective for removing "immature" proliferative membranes and removing pigmented cells from the surface of the retina, which, if left behind, can be a nidus for future membrane formation. Hence, the

present tool may markedly increase the likelihood of success of the ophthalmic surgery.

The invention may be embodied in other specific forms without departing from the spirit or essential characteristics thereof. The present embodiment is therefore to be considered  
5 in all respects as illustrative and not restrictive, the scope of the invention being indicated by the appended claims rather than by the foregoing description and all changes which come within the meaning and range of equivalency of the claims are  
10 therefore intended to be embraced therein.

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